PREMARKET NOTIFICATION

510(k) SUMMARY

JAN 22 2010

(As Required By 21 CFR 807.92)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K093823 Date: DEC 0 9 2009

1. Submitter:

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2. Name of the Device:

Trade Name: Full Automatic (NIBP) Blood Pressure Monitor, Model HL888V, HL868JM
Common Name: Blood Pressure Monitor
Classification Name: Non-Invasive Blood Pressure Measurement System
Classification: Class II
Regulation Number: 21 CFR 870.1130
Product Code: DXN
Panel: Cardiovascular

3. Information for the 510(k) Cleared Device (Predicate Device):

H&L Full Automatic (NIBP) Blood Pressure Monitor, Model HL888BM, K032837

4. Device Description:

Both HL888V and HL868JM are manual inflate type blood pressure monitors for measurement of human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method. All values can be read out in one LCD panel. Measurement

position is at human being's upper arm. The intended use of the over-the-counter device is for adults aged 18 years and older with arm circumference ranging from 9 ~13 inches (approx.23cm-33cm) and for home use.

HL868JM features a Risk Category Indicator additionally. After measurement, the Risk Category Indicator function will show the information with the readings on the screen for the user tracking their blood pressure level.

5. Intended Use

HL888V is a manual inflate type blood pressure monitor for measurement of human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method. All values can be read out in one LCD panel. Measurement position is at human being's upper arm. It is recommended for use by adults aged 18 years and older with arm circumference ranging 9~13 inches (approx.23cm-33cm).

HL868JM is a manual inflate type blood pressure monitor for measurement of human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method. All values can be read out in one LCD panel. Measurement position is at human being's upper arm. It is recommended for use by adults aged 18 years and older with arm circumference ranging 9~13 inches (approx.23cm-33cm).

6. Comparison of device to predicate device:

Product Specification Comparison Table of HL888V and HL888BM (K032837)

Item	Predicate HL888BM (K032837)	HL888V
Method of measurement	Oscillimetric	Same as left
Range of measurement	Pressure 0- 300mmHg, Pulse 40-199 Beats/minute	Same as left
Accuracy	Pressure +/− 3mmHg Pulse +/− 5%	Same as left
Inflation	Manual inflation	Same as left
Exhaust	Manual deflation	Same as left
Deflation of Pressure	Automatic air release control valve	Same as left

Display	Liquid Crystal Digital Display	Same as left
Cuff size	Arm circumference approx. 24~32 cm (9.5~13 inches)	Arm circumference approx. 23~33 cm (9~13 inches)
Sets of memory	48 sets	99 sets
Operating Temperature	10℃ ~40℃ , 30 ~ 85% RH	10℃ ~40℃ (50°F~104°F) , 15% ~90% RH
Storage Temperature	-20℃ ~+50℃ , 10 ~ 95% RH	-20℃ ~+70℃ (-4°F~+158°F), ≦ 90%RH
Power Supply	4 × "AA" (1.5V) Alkaline batteries	One 3V CR2032 battery
Battery life	Approx.300 times measurement	Approx.180 times measurement
Unit Weight	Approx. 265g including batteries	Approx. 100g including batteries

Changes from the predicate device HL888BM (K032837):

Both of HL888V and HL888BM have 4 push buttons and remain the same features such as with date, time, memory, measuring blood pressure and heart rate.

HL888V obtains its energy source from one 3V CR2032 battery, and the inflation bulb was connected with the unit directly. Besides, HL888V is changing the exterior casing design, and the appearance of the symbol "Inflation/Deflation".

Therefore, HL888V does not involve any changes or modifications which could significantly affect or effectiveness of the predicate device, as compared to the HL888BM.

Product Specification Comparison Table of HL868JM and HL888BM (K032837)

Item	Predicate HL888BM (K032837)	HL868JM
Method of measurement	Oscillimetric	Same as left
Range of measurement	Pressure 0- 300mmHg, Pulse 40-199 Beats/minute	Same as left
Accuracy	Pressure +/− 3mmHg Pulse +/− 5%	Same as left
Inflation	Manual inflation	Same as left
Exhaust	Manual deflation	Same as left
Deflation of Pressure	Automatic air release control valve	Same as left
Display	Liquid Crystal Digital Display	Same as left
Cuff size	Arm circumference approx. 24~32 cm (9.5~13 inches)	Arm circumference approx. 23~33 cm (9~13 inches)
Sets of memory	48 sets	99 sets
Operating Temperature	10℃ ~40℃ , 30 ~ 85% RH	10℃ ~40℃ (50°F~104°F), 15% ~90% RH
Storage Temperature	-20℃ ~+50℃ , 10 ~ 95% RH	- 20℃ ~+70℃ (- 4°F~ +158°F), ≦ 90%RH
Power Supply	4 × "AA" (1.5V) Alkaline batteries	2 × "AA" (1.5V) Alkaline batteries
Unit Weight	Approx. 265g including batteries	Approx. 159g without batteries
Battery life	Approx.300 times measurement	Same as left
Risk Category Indicator	None	Yes

Changes from the predicate devices HL888BM (K032837):

Both of HL868JM and HL888BM have 4 push buttons and remain the same features such as with date, time, memory, measuring blood pressure and heart rate.

HL868JM obtains its energy source from 2 "AA" (1.5V) Alkaline batteries. Additional product feature is Risk Category Indicator function. HL868JM is changing the exterior casing design, and the appearance of the symbol "Inflation/Deflation".

Therefore, HL868JM does not involve any changes or modifications which could significantly affect or effectiveness of the predicate device, as compared to the HL888BM.

7. Discussion of Clinical Tests Performed:

Both HL888V and HL868JM are compliant to the ANSI/AAMI SP-10:2002+ A1:2003+A2:2006 Standard for Manual, electronic, or automated sphygmomanometers. All the relevant activities were performed by designate individual(s) and the results demonstrated that the predetermined acceptance criteria were fully met.

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The subject device was tested to evaluate its safety and effectiveness, including the followings:

a. **Safety Test**: IEC 60601-1:1988+A1:1991+A2:1995 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

b. **EMC Test**: IEC 60601-1-2:2001+A1:2004 Medical Electrical Equipment - Part 1-2: General requirements for safety - collateral standard: Electromagnetic compatibility - Requirements and Test

c. **Reliability Test**: ANSI/AAMI SP-10:2002+A1:2003+A2:2006

d. **Risk Assessment**: ISO 14971:2007 Medical devices - Application of risk management to medical devices

e. **Software Verification and Validation**: IEC 62304 Ed. 1.0, Medical device software - Software life cycle processes. (Software/Informatics) and IEC 60601-1-4:2000 Consol. Ed. 1.1, Medical electrical equipment - Part 1-4: General requirements for safety -- Collateral standard: Programmable electrical medical systems

f. **Usability Validation**: IEC 62366 Medical devices - Application of usability engineering to medical devices

9. Conclusions:

The subject device was tested and fulfilled the requirements of those standards mentioned above, and it's concluded that the subject device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN 22 2010

Health & Life Co., Ltd.
c/o Ms. Sarah Su
9F, No. 186, Jian Yi Road
Chung Ho City, Taipei County 23553
TAIWAN R.O.C.

Re: K093823
Trade/Device Name: Full Automatic (NIBP) Blood Pressure Monitor, Model HL888V and Model HL868JM
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: January 12, 2010
Received: January 19, 2009

Dear Ms. Su:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093823

Device Name: Full Automatic (NIBP) Blood Pressure Monitor, Model HL888V, HL868JM

Indications for Use:

HL888V is a manual inflate type blood pressure monitor for measurement of human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method. All values can be read out in one LCD panel. Measurement position is at human being's upper arm. It is recommended for use by adults aged 18 years and older with arm circumference ranging 9~13 inches (approx.23cm-33cm).

HL868JM is a manual inflate type blood pressure monitor for measurement of human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method. All values can be read out in one LCD panel. Measurement position is at human being's upper arm. It is recommended for use by adults aged 18 years and older with arm circumference ranging 9~13 inches (approx.23cm-33cm).

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __V__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Devices Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices

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